PSJ2 Exh 97

Interprofessional Pain Management and Opioid Use:

Ending an Epidemic and Protecting Patient Access

Prescription Drug Diversion and Abuse – Shared Concerns

- Prescription drug diversion and abuse have become an epidemic
- Drug overdose deaths remain significant

- As a result of this epidemic, more people in the United States die from drug overdoses than from car accidents

Prescription Drug Abuse

Prescription drug misuse and abuse is the intentional or unintentional use of medication without a prescription, in a way other than prescribed, or for the experience or feeling it causes.

Substance Abuse and Mental Health Services Administration
www.samhsa.gov/prescription-drug-misuse-abuse

Prescription Drug Abuse

- Misuse vs abuse
  - Mostly has to do with an individual's intentions or motivations
    - Misuse – treating oneself or others not according to health care provider's directions
    - Abuse – taking a drug or higher doses of a drug specifically for a euphoric feeling

Source: Michael Klein, PhD, Food and Drug Administration
www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM220434.pdf

Prescription Drug Abuse

- Tolerance vs addiction
  - Tolerance is a state in which an organism no longer responds to a drug
  - A higher dose is required to achieve the same effect
    - Morphine binds to opiate receptors, which triggers the inhibition of adenylate cyclase and maintains the firing of impulses. After repeated receptor activation, the enzyme adapts so that morphine no longer changes cell firing and the effect of a given dose of morphine or heroin is diminished.

National Institute on Drug Abuse

Prescription Drug Abuse

- Tolerance vs addiction
  - Addiction is a chronic, often relapsing brain disease that causes compulsive drug seeking and use despite harmful consequences to the addicted individual and to those around him or her.

National Institute on Drug Abuse

Prescription Drug Abuse

- Tolerance vs addiction
  - Although the initial decision to take drugs is voluntary for most people, the brain changes that occur over time challenge an addicted person's self-control and hamper his or her ability to resist intense impulses to take drugs.

National Institute on Drug Abuse

Chronic Pain Prevalence

Heart Disease	**25.8 million**
Stroke	**16.3 million**
Cancer	**7 million**
Diabetes	**11.7 million**
Total	**60.87 million**
Chronic Pain	**116 million**

www.painmed.org/patient/facts.html#incidence

Chronic Pain Costs

The total annual cost of health care due to chronic pain ranges from $560 billion to $635 billion.

Source: Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011.

History of Pain Treatment With Opioids

Or, how we got where we are now.

Too Little?
2000

Too Much?
2014

Pain Treatment History

- In the late 1980s, there was a growing perception that pain was being medically undertreated
- Several clinical trials extended this view to noncancerous chronic pain patients
- Physician perception: pain was undertreated, opioids were underutilized, and addiction was not a problem

Pain Treatment History

- In 2000, Congress passed the Decade of Pain Control and Research
- JCAHO (now Joint Commission) released new standards for pain assessment and management
- American Pain Society declared pain as the 5th vital sign
- Patient satisfaction surveys were used widely to measure hospital/physician performance

Epidemic in the Making

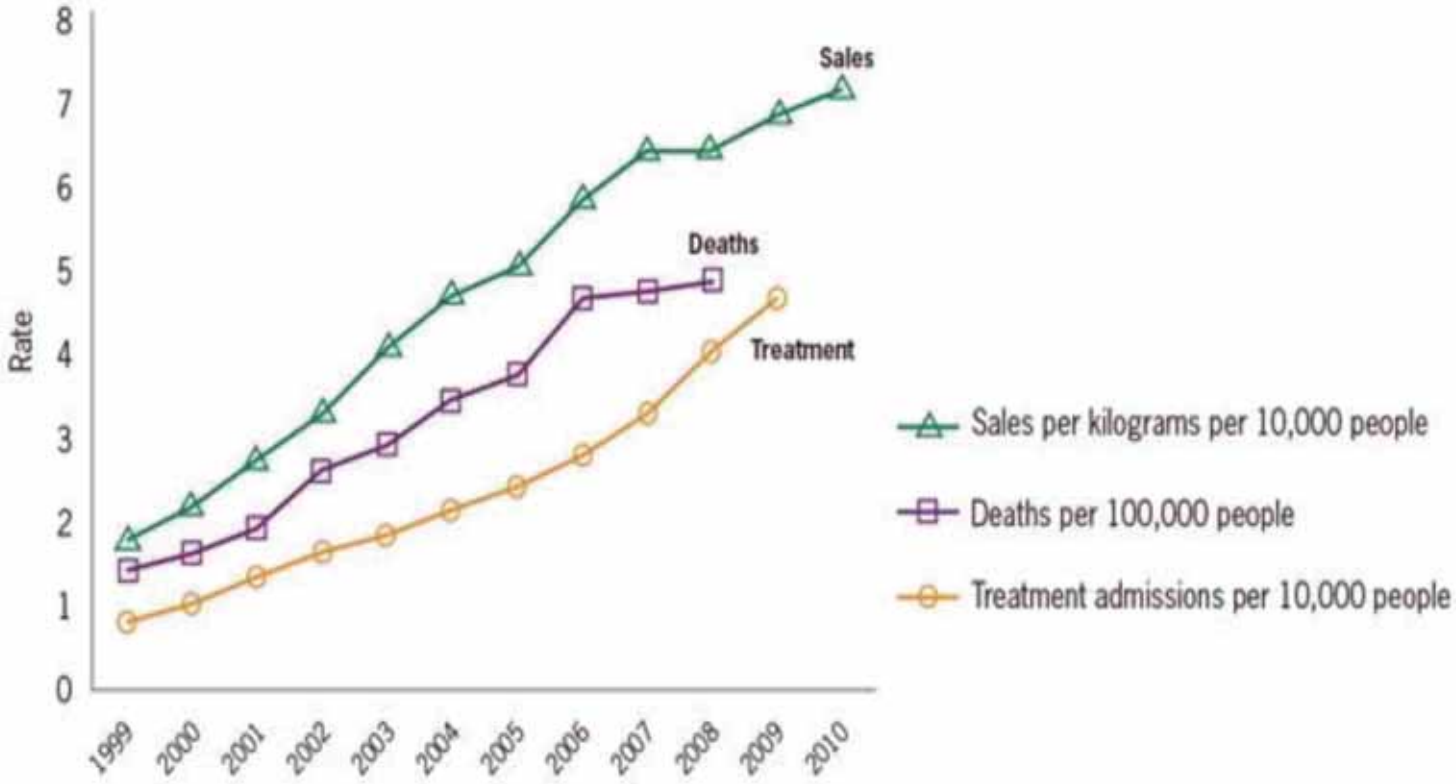
- New, more potent ER/LA opioid formulations were developed along with aggressive pharmaceutical marketing
- Illegal "pill mills" began to proliferate
- Medical and pharmacy schools and residency programs did not provide adequate training on pain management or for treatment of substance use and abuse disorders

Epidemic in the Making

"Deaths from prescription painkillers have reached epidemic levels in the past decade. The number of overdose deaths is now greater than those of deaths from heroin and cocaine combined."

Source: *CDC Vital Signs,* November 2011

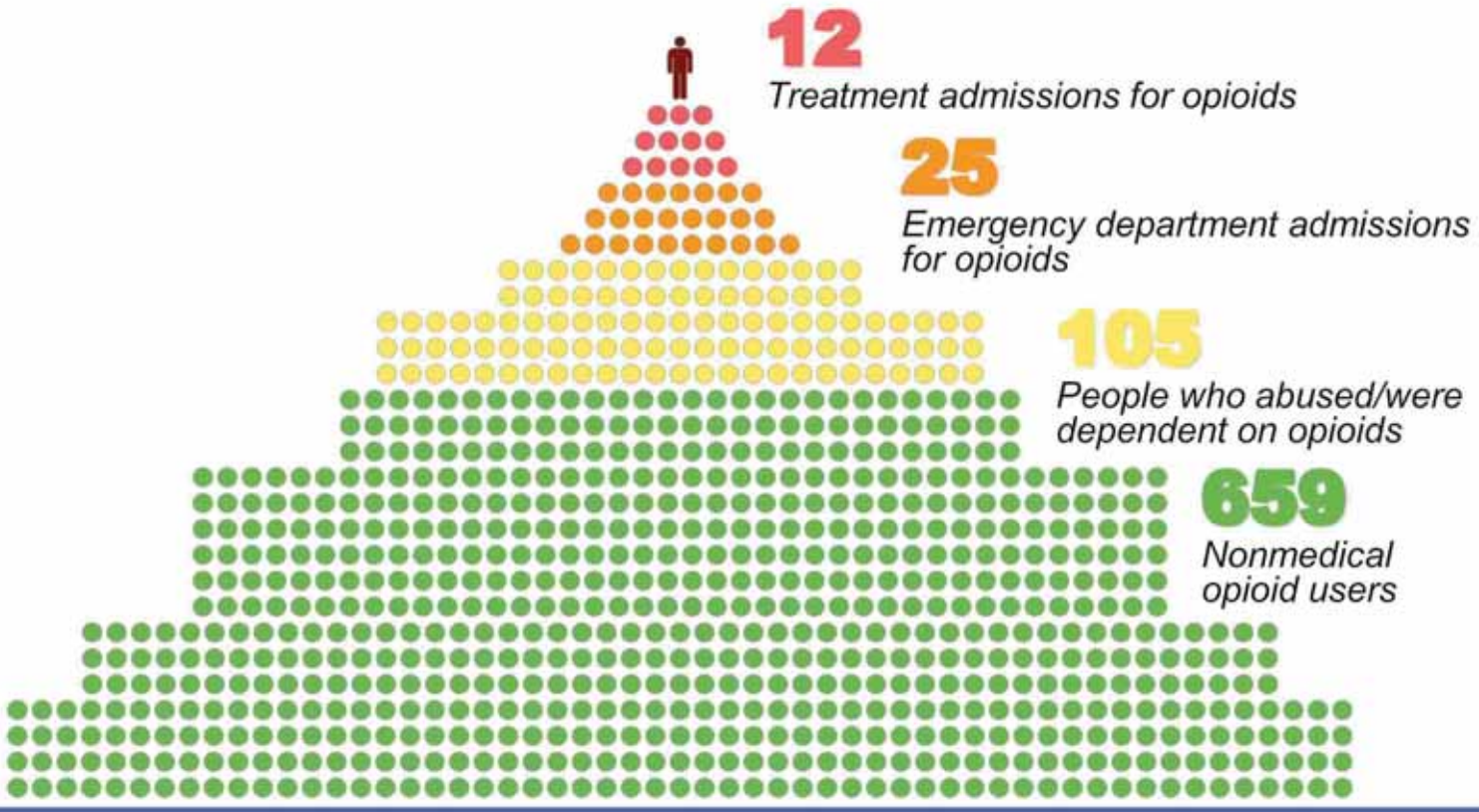
Epidemic in the Making



Sources: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System of the Drug Enforcement Administration, 1999-2010; Treatment Episode Data Set, 1999-2009

Epidemic in the Making

For every 1 prescription opioid overdose death in 2011 there were…



Source: SAMHSA NSDUH, DAWN, TEDS data sets.

Prescription Drug Abuse Treatment Costs

Improper use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

Source CDC *Vital Signs*, November 2011
www.cdc.gov/vitalsigns/painkilleroverdoses

Prescription Drug Abuse Treatment

- Two groups of patients, two sets of needs
  - At risk for addiction/dependence
    - Protect from overexposure to prescription opioids
    - Advocate for alternate treatment options
  - Already addicted/dependent
    - Need access to services

Prescription Drug Abuse Treatment

Two Crises

Over-treatment

Over-use of prescription opioids for chronic pain

Under-treatment

Under-use of medication-assisted treatment (MAT), including buprenorphine and methadone

Pain Management
Health Care Providers' Shared Roles

- Educate patients on safe and effective use of opioids
  - Risks of addiction, overdose/abuse, and proper disposal
- Develop treatment plans in coordination with other health care team members
- Perform and collaborate on medication reviews and ongoing monitoring of patients' medications

Pain Management
Health Care Providers' Shared Roles

- Consult prescription drug monitoring programs (PDMPs) and input applicable data
- Pharmacists in particular
  - Initiate, modify, and discontinue therapy in collaboration, as authorized
  - Provide drug information and medication recommendations to the health care team

Pain Management
Shared Responsibilities

Enforcement:
Prevent diversion

DEA enforcement of federal laws and regulations

Corresponding Responsibility:
Patient legitimate need/access

Finding an appropriate balance

Patient Care:
Pain Management
Addiction Treatment

Collaboration with other health care professionals

Standards of Care and Guidelines

- Opioid risk assessment
- PDMP use
- Document treatment plan
- Document abnormality/deviation from treatment agreement
- Drug screening policy/practices
- Discharge letter (when/if necessary)

Standards of Care and Guidelines

- Centers for Disease Control and Prevention (CDC) Guidelines
  - Dosage recommendations
  - Assessing risks and harms
  - Monitoring and discontinuing
  - Nonpharmacological alternatives

- Various states have adopted additional guidelines
  - AZ, OH, TN, WA, WI

Standards of Care and Guidelines

- Federation of State Medical Boards (FSMB) Model Policy
  - Provides guidance to state medical boards on how to effectively evaluate, assess risk, and document treatment
  - Includes proper referral, patient education, and termination strategies
  - Highlights the need to comply with proper state and federal laws

Standards of Care and Guidelines

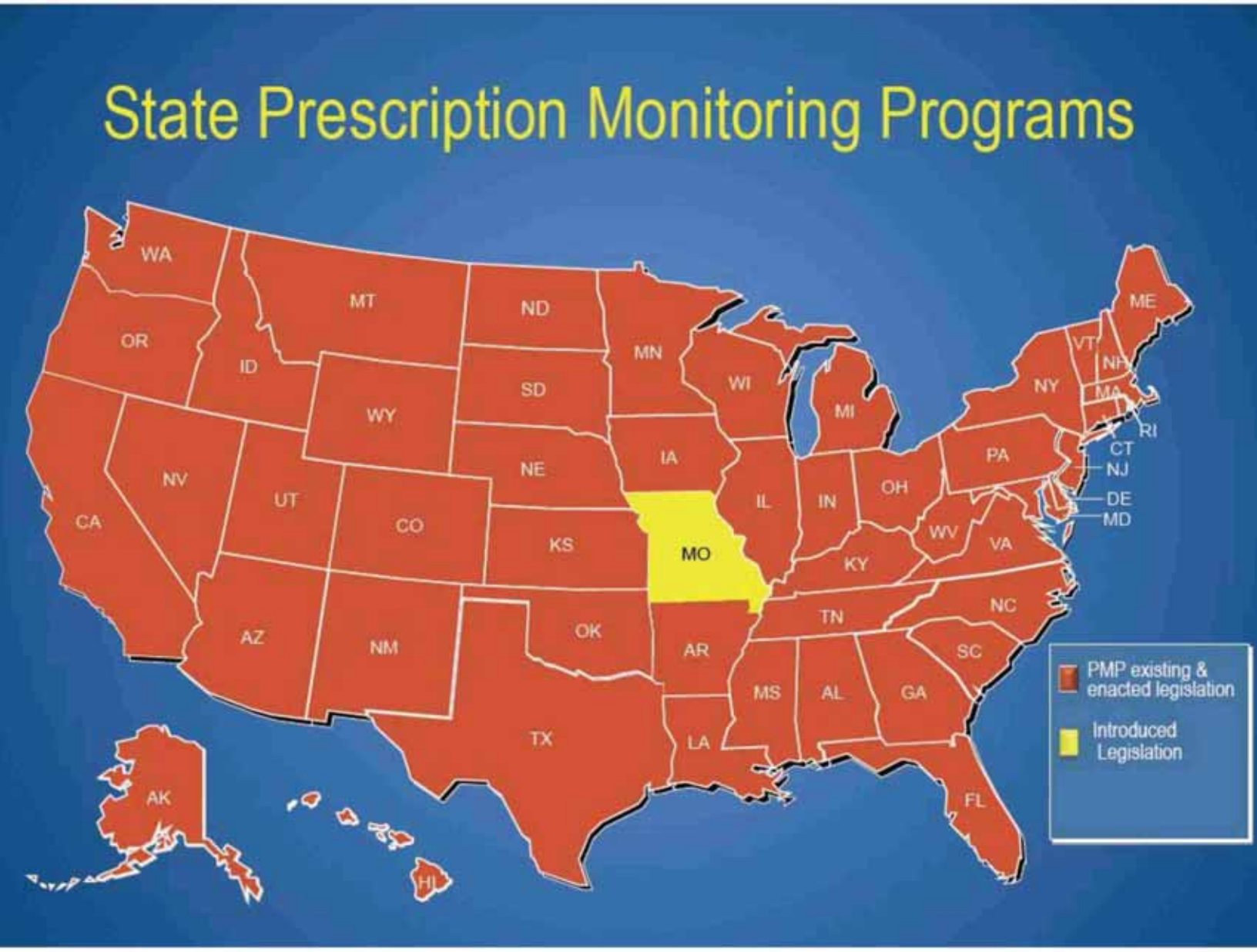
- FSMB Model Policy
  - The revised FSMB Model Policy makes it clear that state medical boards will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices.

Standards of Care and Guidelines

- Corresponding Responsibility Doctrine
  - Pharmacists are accountable for improperly prescribed/dispensed medications.
  - Drug Enforcement Administration (DEA) mandates that pharmacists assess "whether prescriptions for controlled substances were written for a legitimate medical purpose in the usual course of professional practice."
  - A pharmacist must determine a prescription meets these criteria prior to dispensing.

Standards of Care and Guidelines

- Corresponding Responsibility Doctrine (cont.)
  - Assess patient's actions – "red flags"
  - Consult patient records to identify trends
  - Consult PDMP if available
    - Accessibility and updates
  - Validate information
    - Patient and DEA registration
  - Ask about other medications patient is taking
  - Consult and collaborate to verify prescription


State Prescription Monitoring Programs
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
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SD
NE
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OK
TX
MN
IA
MO
AR
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MI
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KY
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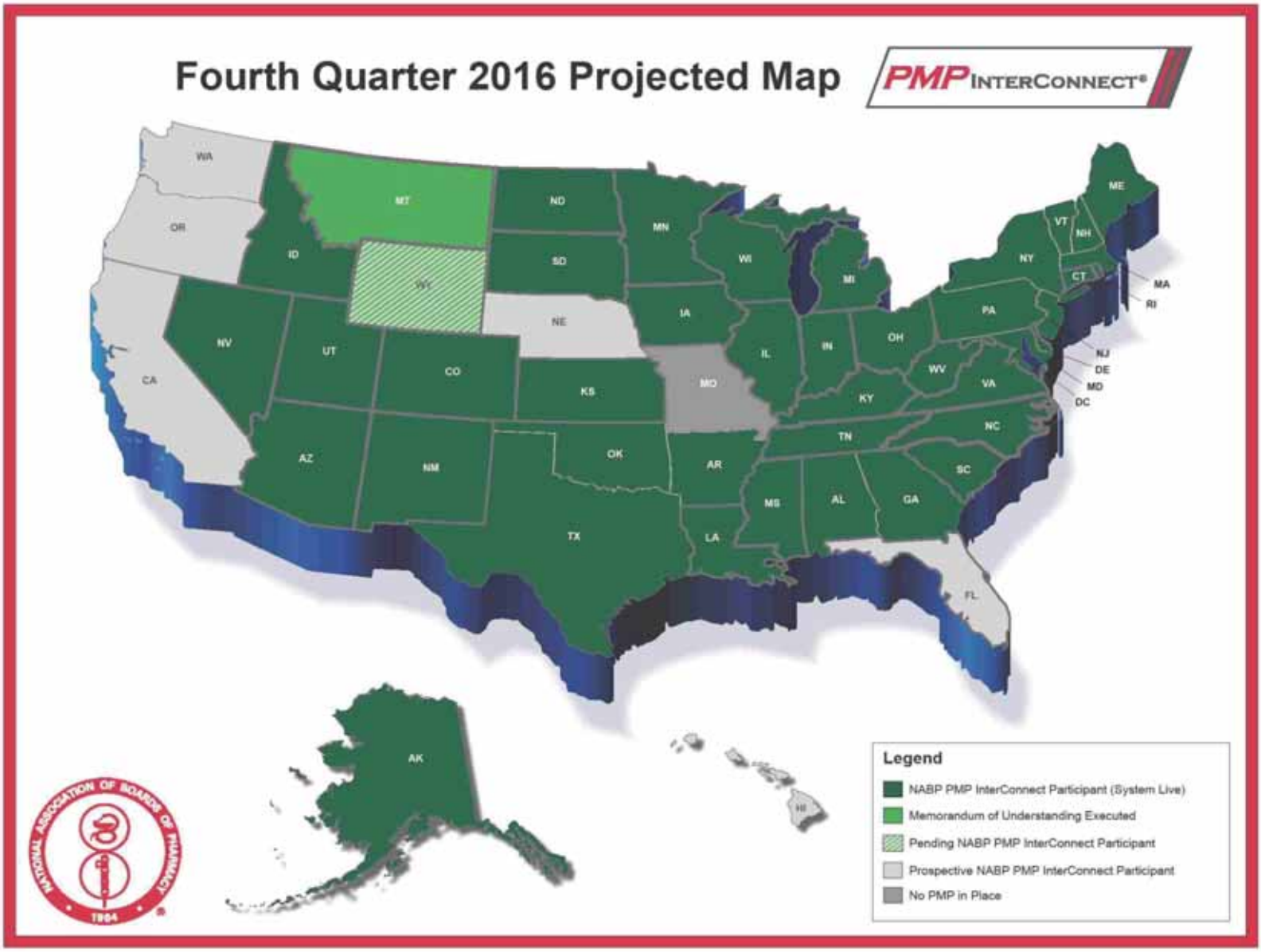
AL
OH
WV
GA
FL
SC
NC
VA
PA
NY
ME
VT
NH
MA
RI
CT
NJ
DE
MD
AK
HI
PMP existing & enacted legislation
Introduced Legislation


Fourth Quarter 2016 Projected Map
PMP InterConnect®
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MS
MI
IN
KY
TN
AL
OH
WV
GA
FL
SC
NC
VA
PA
NY
MD
DE
NJ
CT
RI
MA
VT
NH
ME
DC
AK
HI
Legend
NABP PMP InterConnect Participant (System Live)
Memorandum of Understanding Executed
Pending NABP PMP InterConnect Participant
Prospective NABP PMP InterConnect Participant
No PMP in Place

Challenges

- Patient access to care
  - Delay in dispensing legitimate prescriptions
  - Unable to obtain required medications
  - Risk of withdraw without access to prescriptions needed to address pain

Challenges

- Pharmacy Issues
  - Effectively managing pain and complying with legal requirements – corresponding responsibility
  - Limited access to complete and pertinent information
  - Distribution limits on controlled substance quantities

Challenges

- Practitioner and pharmacy issues
  - Safety
    - Robbery targets
    - Patient aggression and intimidation
  - Patient satisfaction surveys
    - Not prescribing opioids may negatively impact surveys, which are increasingly being used for performance incentives and public report cards

Challenges

- Diversion Activities
  - Forged prescriptions
    - Stolen prescription pads
    - Phone-in prescriptions posing as doctor's office
  - Altered legitimate prescriptions
    - Change quantities to larger supplies
    - Photocopy prescriptions
  - Cash payment for prescriptions
  - Request refills too early

Source: The National Center on Addiction and Substance Abuse National Survey of Pharmacists

Progress
NABP Stakeholders Coalition

- Convened by the National Association of Boards of Pharmacy
- Organized medicine (AMA, AOA, AAFP)
- Organized pharmacy (APhA, ASHP, NCPA, NACDS)
- Several large pharmacy chains
- Wholesalers, manufacturers
- DEA

Fostering Physician-Pharmacist Collaboration: Patient Case

Case Study

- 46-year-old female, diagnosis: fibromyalgia
- 2013 – seeing multiple physicians, psychiatrist, numerous emergency department (ED) visits
- Medications include: hydrocodone/ acetaminophen, gabapentin, carisoprodol, venlafaxine, alprazolam
- Pharmacist referred her to a local family practice provider for all non-psychiatric medications, further referral to rheumatologist

Case Study

- Non-adherence problems, including over- and under-adherence
- 2014 – adherence packaging instituted with one-week bubble packs
- All pain medications now from rheumatologist

Case Study

- Positive Outcomes
  - Improved pain control
  - Improved adherence
  - Reduced psychiatric medications
  - Reduced ED visits
- All providers have current medication lists provided by pharmacy

Future Guidelines for Practitioners

Guidelines endorse evidence-based integrative therapies for chronic non-cancer pain, including cognitive-behavioral therapy and other non-pharmacological therapies, should be recommended and covered by payers.

Future Guidelines for Practitioners

- Guidelines should continue to promote alternatives to opioids (osteopathic manipulative therapy, physical therapy)
- Alternative therapies should be covered when opioids are ineffective or inadvisable
- Urine and pharmacogenetic testing should be covered by all payers to increase use by practitioners
- Personalized therapy should be main focus

Source: Webster, L., "Safeguarding Integrity in Opioid Clinical Practice", Pain Medicine News, Aug 2015, Vol: 13(8)

Future Goals

- Combat misuse and diversion
- Educate both practitioners and pharmacists on “red flags”
- Address concerns of each group
  - Practitioners – scope of practice
  - Pharmacists – corresponding responsibility requirements
- Increase appropriate communication
- Foster interprofessional collaboration

Future Goals

- Widespread availability of Food and Drug Administration-approved abuse-deterrent formulations
- Increased studies of ways to mitigate non-medical use during pregnancy and evidence on opioids and birth defects
- Better understanding of severe, noncancerous chronic pain and the benefits and risks of long-term opioid use should be evidence-informed

Future Goals

- Full PDMPs utilization and collaboration
- Advocate for incentives that support successful models
- Maximize e-prescribing of controlled substances
  - Avoids some of the methods used to divert these medications
  - Allows for additional information to be delivered to pharmacists

Future Goals

- Practitioner-Pharmacist Collaborations
  - Improve practitioner-pharmacist communications
    - Identify successful approaches that minimize administrative burden
    - Optimize use of health information technology to facilitate communications

Future Goals

- Practitioner-Pharmacist Collaborations
  - Practitioners and pharmacists can reinforce patient education, risk awareness, disposal methods
  - Enhance sharing of relevant information
    - Pharmacists often must make assessments of potentially abusive behaviors with incomplete medical information, such as diagnoses
    - Sharing of treatment agreements/contracts with the pharmacist could assist in patient monitoring

Summary

- Chronic pain is a widespread and extremely costly medical problem
- Skyrocketing opioid use, abuse, and overdose deaths have become an epidemic
- Many new laws, regulations, and guidelines have been enacted, proposed, and promoted

Summary

- All practitioners and pharmacists need to work together
  - Address prescription drug misuse, abuse, and diversion
  - Ensure patient access to care, including prescription drugs when necessary

Notes Summary:

Slide 9: 'These figures combine the medical costs of pain care and the economic costs related to disability days and lost wages and productivity.'

Notes Summary:

Slide 11: 'During the past two-plus decades, growing numbers of patients with persistent non-cancer pain have been offered long-term opioid therapy. This change in prescribing behavior has been influenced by several competing interests. The roots of this problem go back to the mid 1980s.

In the 1980s and early 1990s, a great deal of attention was devoted to improving the management of cancer pain and post surgical pain (Government Guidelines from AHCPR, the forerunner to AHRQ). During the same time period, attention also shifted to patients with chronic non-cancer pain. The aggressive use of opioid analgesics was endorsed as the most effective approach to address patient suffering in patients with cancer-related pain.

Several short-term, randomized, controlled trials, clinical surveys, uncontrolled retrospective surveys, and case series on opioid use in patients with chronic non-cancer pain were published. A subset of patients in these studies appeared to benefit from opioid therapy. Prescribing Guidelines and physician attitudes eventually became aligned with the view that long-term opioid therapy is beneficial in the treatment of selected patients with chronic non-cancer pain, such

Notes Summary:

therapy may be underutilized, and addiction is generally not a significant concern. Training in medical school and residency did nothing to discourage this practice.

With the advent of a new array of potent extended-release and long-acting prescription opioid products, as well as aggressive pharmaceutical marketing, this approach was further extended to patients with persistent non-cancer pain, despite a lack of evidence obtained from long-term, randomized controlled trials (which are not feasible).

In both the hospital and outpatient settings, the recognition of pain as the 5th vital sign, the evolution of patient satisfaction surveys that include a focus on the extent to which a patient's pain is relieved, and new pain standards from the Joint Commission served as powerful incentives to provide opioid analgesics.

A lack of access to multidisciplinary care, inadequate access to and reimbursement for nonpharmacologic approaches to pain management, and inadequate training in pain management/substance use disorder across the continuum of medical education all contributed to a practice

Notes Summary:

environment that promoted routine opioid use for pain management; yet national attention was refocused on the burden imposed by chronic pain affecting the United States population (IOM Report).

Consequently, over the last 15 years, the rate of opioid prescribing, especially for patients with chronic non-cancer pain has increased dramatically. In 2014, more than 244 million prescriptions for opioid analgesics were written in the US. It is estimated that between 9.6 to 11.5 million Americans are currently being prescribed long-term opioid therapy.

- Over the last 15 years, opioid prescribing has increased four-fold.
- A similar four-fold increase has occurred in the number of deaths associated with the use of prescription opioids; 145,000 prescription opioid deaths in 10 years.
- A concomitant increase in treatment admission for opioid dependence also occurred.
- Some leveling off in the number of deaths from prescription opioids has occurred between 2007 and 2013 (7.6% increase), but a large increase in heroin overdoses and deaths has occurred over the same time frame, particularly over the last few years.

Notes Summary:

- The combined total of overdose deaths from prescription opioids and heroin continues to increase.

These trends in opioid prescribing occurred despite a general lack of confidence among physicians to safely prescribe opioids, to detect or discuss prescription drug misuse with their patients, to acknowledge that prescription drug abuse is a problem in their community, have a personal experience with tolerance and physical dependence developing their patients, and air concerns about possible addiction and death.'
Slide 12: 'Inadequate access to and payment for, nonpharmacologic approaches to pain management also contributed to a practice environment that promoted routine opioid use for pain management.
National attention was refocused on the burden imposed by chronic pain affecting the US population (IOM Report).
JCAHO = Joint Commission on Accreditation of Healthcare Organizations'
Slide 13: 'ER = extended release
LA = long-acting'

Notes Summary:

Slide 20: 'Educate patients on safe and effective use of opioids
Drug-disease interactions (eg, sleep apnea and respiratory depression)
Drug-drug interactions (eg, hydrocodone and macrolide antibiotics)

Interview the patient and analyze data from patient-controlled analgesia devices as a tool to determine the appropriate dose'
Slide 22: 'DEA focuses attention to trail the enforcement to the pharmacy as the last point where patient care safety can be impacted.

Both physician and pharmacists are in difficult positions; however More than any other provider, the pharmacist may be in the more difficult position (verification of right patient, leg Rx, etc).

Slide 14 (Balancing) or Slide 23 (here) - NABP coalition did stem from the AMA House of Delegates (May or June 2015) passing a resolution preventing the pharmacist's intrusion into medicine.'

Notes Summary:

Slide 24: 'There are significant concerns that do exist within the medical community with these guidelines, the way there were developed, that lack of input and review by outside experts, and the use of any dosage recommendations that fail to take into account individualized care that meets the needs of each patient.'
Slide 29: 'Discuss trends toward mandatory use of PDMPs for practitioners and dispensers.'
Slide 30: 'Discuss need for states to share data and federal proposals to increase data sharing through grants.'

Notes Summary:

Slide 35: 'American Academy of Family Physicians
American College of Emergency Physicians
American Medical Association
American Osteopathic Association
American Pharmacists Association
American Society of Anesthesiologists
American Society of Health-System Pharmacists
Cardinal Health
CVS Health
Healthcare Distribution Management Association
National Association of Boards of Pharmacy
National Association of Chain Drug Stores
National Community Pharmacists Association Pharmaceutical Care Management Association
Purdue Pharma L.P.
Rite Aid
Walgreen Co'

Notes Summary:

Slide 40: 'Opioids are imperfect options for all pain states and yet are the only treatment that works for many acute, sub-acute, and chronic pain conditions. Whenever possible, an equally efficacious therapy should be recommended, even if it costs more.

And while there are alternative solutions, they also need more evidence that these approaches work for chronic pain; they have the same evidence limitation as opioids: no randomized studies for longer than 1 year.'
Slide 41: 'Guidelines should be directed toward public and private insurance payers, as well as providers, indicating which therapies should be covered when opioids are ineffective or inadvisable.
Urine drug and pharmacogenetic testing should be covered by all payers and used by practitioners.
Guidelines should allow for personalized therapy, recognizing that not all mu-opioid agonists work the same way in all patients.'

Notes Summary:

Slide 43: 'Abuse-deterrent formulations that are FDA-approved should be made available to all patients who require extended-release (ER) opioids at equal cost to a generic ER formulation. Recognizing that abuse deterrent formulations do not prevent abuse via the oral route; CDC failed to make a recommendation.

The evidence that opioids cause birth defects is inconclusive and should be accompanied with guidance on the risks of unrelieved pain and the use of alcohol and other pain medications, including nonsteroidal anti-inflammatory drugs, during pregnancy.

Severe pain should be understood to persist in some people; those who are on opioids for more than 90 days are at increased risk for disability for reasons other than opioids; guidelines should not state or imply that opioids are the reason for the disability without supporting evidence.'